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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,897	07/30/2003	Itaru Sakou	1448.1042	6247
21171 7590 12/27/2007 STAAS & HALSEY LLP SUITE 700 1201 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER LIN, JERRY	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 12/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/629,897

Applicant(s)

SAKOU, ITARU

Examiner

Jerry Lin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 25, 26, 28, 29 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) 3-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 25, 26, 28, 29, and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Applicant's arguments and amendments, filed October 9, 2007, have been fully considered and they are deemed to be persuasive in part. However, in light of the amendments, the following rejections are either reiterated or newly applied as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

2. Amended claim 3 is directed to an invention that is independent or distinct from the invention originally elected species for the following reasons: Applicants originally elected Species A, original claim 3, as it was drawn to calculating a distance between the start position of the first gene and the start position of the second gene. However, claim 3 is now amended to recite calculating a first distance between a target gene and a first gene and a second distance between a target gene and a second gene. Species A is independent or distinct from the amended claim 3 because the different versions of claim 3 relate to the different species that recite the mutually exclusive characteristics of each species. In addition, these species are not obvious variants of each other based on the current record.

Since applicant has received an action on the merits for the originally elected species, claim 3 is withdrawn from consideration as being directed to a non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of the Claims

Claims 1, 2, 25, 26, 28, 29, and 31-33 are under examination.

Claims 3-11 are withdrawn.

Claim Rejections - 35 USC § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 2, 25, 26, 28, 29, and 31-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement in light of Cohen et al. (Nature Genetics, October 2000, Volume 26, pages 183-186). The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include:

(1) the quantity of experimentation necessary – According to Cohen et al., further experimentation is needed to determine the expression site from distance. See below for discussion.

(2) the amount of direction presented – The specification does not teach how the distance between genes will necessarily allow the prediction of a gene expression site or how to derive a distance from the ratios that define sensitivity or specificity.

(3) the presence or absence of working examples – Although the specification does provide examples, the examples do not include teachings of how the distance between genes will necessarily allow the prediction of a gene expression site or how to derive a distance from the ratios that define sensitivity or specificity.

(4) the nature of the invention – The invention is drawn to supporting a user in predicting a gene expression site by calculating a distance between a unknown gene and known genes and comparing that distance to a predetermined distance based on sensitivity and specificity.

(5) the state of the prior art – The prior art teaches that distance is not predictive of gene expression sites.

(6) the relative skill of those in the art – The level of skill of those in the art is high.

(7) the predictability or unpredictability of the art – Predicting where genes are expressed is unpredictable.

(8) the breadth of the claims – The claims are drawn to particular computational method of predicting a gene expression site.

The instant specification teaches that the determination of the gene expression site is based on the distance between the unknown gene and known genes (page 5, lines 9-14). Furthermore, the specification teaches that if the distance meets a

threshold distance from a known gene, the expression site of the unknown gene may be predicted (pages 17-18), since it would share the expression site of the known gene (i.e., coexpressed). However, one of skill in the art would not know how the distance between a known gene and an unknown gene will necessarily result in the prediction of the expression site of the unknown gene. For example, Cohen et al. teach the correlation between the distance between genes and the likelihood those genes will be coexpressed. Although Cohen et al. do teach that the closer ORFs are together, the more likely they will be coexpressed, Cohen et al. also states that "the distance between ORFs is not in itself a predictive of increased correlation." (page 184, right column, 2nd full paragraph). In other words, although the distance between genes may show a trend of coexpression, that trend does not predict whether a gene is coexpressed with a known gene. Since the trend does not necessarily lead to a prediction of gene expression sites, one of skill in the art would have to perform undue experimentation in order to determine the gene expression site of an unknown gene. Because the information from the claimed method does not provide any information that allows the prediction of gene expression site, this method does not provide support for predicting a gene expression site. Thus without further guidance from the specification or method steps, one of skill in the art would not be enabled to use the invention as claimed to predict expression sites without undue experimentation.

Applicants have also amended the claims to include a predetermined distance relation or threshold based sensitivity and specificity. According to page 17 of the specification, sensitivity is defined as $A/(A+B)$ where A is the number of expression sites

of a unknown gene determined by another method that have been predicted and B is the number of expression sites of a unknown gene determined another method that have been not been predicted. Specificity is defined as $b/(a+b)$ where a is the number of non-expression sites of a unknown gene determined another method that have been predicted and B is the number of non-expression sites of a unknown gene determined another method that have been not been predicted. However, the ratio that defines specificity and sensitivity do not appear to have a term in the equation that relates to distance. Thus, one of skill in the art would not know how to determine distance from these equations. Without further guidance from the specification or method steps, one of skill in the art would not be enabled to use the invention as claimed to support a user to predict expression sites without undue experimentation.

Response to Arguments

5. In response to this rejection, applicants have amended the instant claims to recites "A method for supporting a user in predicting a gene expression site. . . ." It is established in the prior art that distance between genes does not predict gene expression sites (see above). In order to predict gene expression sites, one of skill in the art must conduct further undue experimentation beyond determining the distance between genes. Given that one of skill in the art cannot predict a gene expression site from the distance between genes and that the instant claims are drawn to determining a gene expression site base on distance, the limitation of "supporting a user in predicting

a gene expression site" is an invitation for conducting further undue experimentation.

Thus, the invention as claimed is not enabled.

Furthermore, it is noted that instant claims 1, 25, 28 and 33 recite determining a first gene expression site of the first gene based on distance, which as explained above, require further experimentation and research.

This rejection is maintained from the previous office action and modified as necessitated by amendment.

6. Claims 1, 2, 25, 26, 28, 29, and 31-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The instant claims were amended to recite that the claimed method is "for supporting a user in predicting a gene expression site" as opposed to "a method for predicting gene expression sites." However, the limitation of "supporting a user" does not appear anywhere in the specification. Rather, the specification clearly states "The present invention relates to a method, program, and apparatus for predicting gene expression sites of a gene whose expression site is unknown on a genome sequence." (page 1, lines 5-8). Thus, the limitation of "supporting a user" is NEW MATTER.

This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 112, 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 2, 25, 26, 28, 29, and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, 26, and 29, the instant claims recite "the distance." It is unclear which distance are the instant claims referring to in the parent claim. This rejection is necessitated by amendment.

Claim 31 recites the limitation "the list" in line 2. There is insufficient antecedent basis for this limitation in the claim. This limitation is not mentioned previously in the instant claim or in the claim from which it depends. This rejection is necessitated by amendment.

Instant claim 31 recites "the second site." However, there are multiple second sites in the parent claim. It is unclear to which second site is the instant limitation referring. This rejection is necessitated by amendment.

9. Claims 1, 2, 25, 26, 28, 29, and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps required to determine the expression sites of the first gene based on distance and the steps required to determine a predetermined distance relation using sensitivity and

specificity. Calculating the distance between genes on a genome sequence does not in itself determine the expression sites of a gene. Further processing or data manipulation is required in order to use the distance between genes to find the expression site of a gene.

In addition, sensitivity is defined as a ratio of expression sites predicted to expression sites previously determined that it is where the unknown gene expression by another method (specification, page 16). Specificity is defined as the ratio of expression sites not predicted to expression sites previously determined that it where the unknown gene never expresses by another method (specification, page 16). It is unclear what further steps are required to derive a distance from the ratios that define sensitivity and specificity.

Response to Arguments

10. Applicants have responded to this rejection by amending the claims. However, as explained above, it remains unclear what other steps are required to determine a first gene expression site, as in the second step of claims 1, 25, 28 and 33, from calculating a distance.

This rejection is maintained from the previous office action and modified as necessitated by amendment.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1, 2, 25, 26, 28, 29, and 31-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 2, and 31-33 are drawn to a process involving the judicial exception of a computational algorithm. Claims drawn to a judicial exception is non-statutory unless the claims include a practical application of that judicial exception as evidenced by a physical transformation of the claimed invention, or if the claimed invention produces a useful, tangible and concrete final result. In the instant claims, there is no physical transformation by the claimed invention, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result. See MPEP 2106.

The instant claims do not produce a tangible final result. The tangible final result requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The instant claims are drawn to a method of determining gene expression sites from distance. However, the last step of the claims is a compiling step, which indicates there is an ongoing process. This final step of outputting does not necessarily indicate that a final result has been communicated to a user. For example, the method, as claimed, may take place entirely within the confines of a computer or the human mind without any communication to the outside world. Thus, instant claims do not include a tangible final result. This rejection could be overcome by amendment of the claims to identify/recite a concrete result and to recite that the result is outputted to a display or to a user or outputted in a user

readable format. However, applicant is reminded that any amendment must be fully supported and enabled by the originally filed disclosure.

Claims 25, 26, 28, and 29 are drawn the method of claim 1 embodied on an apparatus or computer readable medium. The method embodied in claims 25, 26, 28, and 29 are drawn to a judicial exception and still requires a practical application. As explained above, the method does not have a practical application.

In addition, claims 25 and 26 have been amended to be drawn to a computer readable medium. Read broadly, a computer readable medium includes carrier waves which are non-statutory *per se*. Thus, the instant claims are non-statutory.

Response to Arguments

13. Applicants have responded to this rejection by including a step of outputting in the instant claims. However, outputting may include outputting to a processor or to another process or to another computer, etc. Outputting does not necessarily mean that the final result is tangible. Thus, the instant claim includes non-statutory embodiments and must be rejected as being non-statutory.

This rejection is maintained from the previous office action and modified as necessitated by amendment.

14. Claims 1, 2, 25, 26, 28, 29, and 31-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The instant claims are drawn to supporting a user in predicting a gene expression site by calculating a distance between an unknown gene and known genes and comparing that distance to a predetermined distance based on sensitivity and specificity. However, as explained above, distance cannot be used to determine the gene expression site without further experimentation or research. Thus, for one of skill in the art to predict a gene expression site, one of skill must conduct further experimentation or research. The limitation of "supporting a user in predicting a gene expression site" is an invitation to conduct further experimentation or research. Utilities that are an invitation to conduct further experimentation or research are not substantial utilities. Thus, the instant claims do not have a substantial asserted utility.

Furthermore, a search of the prior art has not revealed any well-established utilities.

This rejection is necessitated by amendment.

15. Claims 1, 2, 25, 26, 28, 29, and 31-33 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

This rejection is necessitated by amendment.

Withdrawn Rejections

16. Applicant's arguments and amendments, filed 10/9/2007, with respect to the rejection made under 35 U.S.C. 102(b) as being anticipated by Salgado et al. have been fully considered and are persuasive. Salgado et al. do not teach using sensitivity and specificity to determine a distance relation. This rejection has been withdrawn.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/

/Marjorie A. Moran/
SPE, AU 1631
12/20/2007